



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,711	01/27/2004	W. James Jackson	2479.004003/EJH/C-K	4900
26111	7590	08/10/2007	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			BASKAR, PADMAVATHI	
		ART UNIT	PAPER NUMBER	
		1645		
		MAIL DATE	DELIVERY MODE	
		08/10/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,711	JACKSON ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 19 April 2007.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2,13,16,21,22 and 27-82 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 2,13,16,21,22, and 27-82 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/04 and 11/17/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed on 4/19/07 is acknowledged and has been entered. Applicant provisionally elected sequence at least 95% identical to amino acids 217 - 674 of SEQ ID NO: 2. Applicant states that claims 2, 16, 21, 22, 38-59 and 71-82 are readable on the elected invention. Upon review and reconsideration, it is found that applicant is correct and all pending claims will be examined, but examined only as they are drawn to a polypeptide comprising the elected SEQ.ID.NO:2.

Applicant states that the examiner is incorrect in stating the status of the claims in page 2. The examiner indicated correctly the status of the pending claims in page 1 of the previous office action not in page 2. It is regretted the oversight made in para # 3 (a) for typographical error for amino acids 29-253 and should have been 29-533.

Status of Claims

2. Claims 2, 13, 16, 21, 22, and 27-82 are pending and are currently under examination

Information Disclosure Statement

3. The Information Disclosure Statements (IDS) filed on 1/27/04 and 11/17/06 have been reviewed and a signed copy of each is attached to this office action.

Claim Rejections - 35 USC 112, first paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 2, 13, 16, 22, 27-37, 38-48, 49-59, 60-70, 71-72, 74-82, are rejected under 35 U.S.C. 112, first paragraph , as lacking an adequate written description in the specification.

Claims are drawn to an isolated polypeptide and a composition comprising an amino acid sequence at least 95% identical to SEQ.ID.NO:3,17 or 25-37 or amino acids 29-533 of SEQ ID NO: 2 , 217-674 of SEQ ID NO: 2, 688-1012 of SEQ ID NO: 2 or "an amino acid sequence thereof ", wherein said polypeptide is recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 (polypeptide with 95% identity or fragments of SEQ.ID.NO:2 are considered as variants of SEQ ID NO: 2..

The state of the art with respect to variant polypeptide teach (Bowie et al ,Science, 1990, 257:1306-1310) that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing

Art Unit: 1645

predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (col 1, p. 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (col 2, p. 1306). In particular, the exquisite sensitivity of antibody binding to alterations of even a single amino acid is well known in the art. For example: Coleman et al. (Research in Immunology, 1994; 145(1): 33-36) teach single amino acid changes in an antigen can effectively abolish antibody antigen binding. Furthermore, Abaza et al. (Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444, see abstract in particular) teach single amino acid substitutions outside the antigenic site on a protein affects antibody binding. These references demonstrate that even a single amino acid alteration or what appears to be an inconsequential chemical modification will often dramatically affect the biological activity and characteristics of a binding protein. Clearly, if these structural changes affect the biological activity and characteristics of a binding protein in its ability to bind, it would also be expected that structural alterations, even with a single amino acid, would also change the biological activity and binding characteristics of an antibodies produced in by immune response to the polypeptide, wherein the specification does not provide a written description of the claimed polypeptide that is recognized by an antibody that specifically binds to the amino acid sequence of SEQ.ID.NO:2

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Art Unit: 1645

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristicsi.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.' Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. Thus, the instant specification may provide an adequate written description of the an isolated polypeptide comprising an amino acid sequence of at least 95% identical to amino acids 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 or an amino acid sequence of SEQ.ID.NO: 2 per Lilly by structurally describing a representative number of variant polypeptide recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe isolated polypeptide comprising an amino acid sequence of at least 95% identical to amino acids 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 or an amino acid sequence of SEQ.ID.NO: 2 recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of isolated polypeptide comprising

isolated polypeptide comprising an amino acid sequence of at least 95% identical to amino acids 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 or an amino acid sequence of SEQ.ID.NO: 2 because it does not disclose which 5% amino acids of 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or SEQ.ID.NO: 3, 17, or 25-37 are changed to obtain peptide with 95% identical to amino acids 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 nor does the specification provide any partial structure of such polypeptide nor any physical or chemical characteristics of said polypeptide nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single isolated polypeptide consisting of the amino acid sequence SEQ.ID.NO: 2 this does not provide a description of an isolated polypeptide comprising 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 that would satisfy the standard set out in Enzo.

The specification also fails to describe isolated polypeptide comprising 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 or an amino acid sequence of SEQ.ID.NO: 2 recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the SEQ.ID.NO: 2 by the test set out in Lilly. The specification describes only a single isolated polypeptide consisting of amino acids of SEQ.ID.NO: 2. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of isolated polypeptide comprising 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 or an amino acid sequence of SEQ.ID.NO: 2 that is required to practice the claimed invention. Since the specification fails to adequately describe the product, isolated polypeptide comprising 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37, it also fails to disclose the composition comprising isolated polypeptide comprising 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 to comply with 35 USC 112, first paragraph because it is not supported by an adequate written description in the specification. Thus these claims are also not adequately supported by an adequate written description.

please note that the limitations drawn to the recognizability of the claimed polypeptides by antibodies that bind to SEQ ID NO:2 is not a function of the polypeptide claimed, rather it is a

Art Unit: 1645

function of the antibody that does the recognizing. The ability to be recognized is simply a physical characteristic of the claimed polypeptide, that is, it comprises amino acids that are recognizable.

7. Claims 2, 13, 16, 22, 27-37, 38-48, 49-59, 60-70, 71-72, 74-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polypeptide comprising the amino acid sequence , SEQ ID NO:2, and a composition comprising said polypeptide, said composition further comprises adjuvant mLT does not reasonably provide enablement for an isolated polypeptide isolated polypeptide comprising 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 or an amino acid sequence of SEQ.ID.NO: 2 wherein said polypeptide is recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2 (considered as variant polypeptide 217-674 of SEQ ID NO: 2). The specification fails to provide an enabling disclosure for the full scope of claimed polypeptide variant because it fails to provide any guidance regarding how to make and use claimed antibody that bind to unknown variants.

Claims are drawn to an isolated polypeptide and a composition comprising an amino acid sequence at least 95% identical to SEQ.ID.NO:3,17 or 25-37 or amino acids 29-533 of SEQ ID NO: 2 , 217-674 of SEQ ID NO: 2, 688-1012 of SEQ ID NO: 2 and 29-1012 of SEQ.ID.NO:2 or an amino acid sequence of SEQ.ID.NO: 2, wherein said polypeptide is recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO:2.

The instant claims are evaluated for enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification teaches preparation of recombinant polypeptide from Chlamydia trachomatis serovar LGV L2 , identified as SEQ.ID.NO:2 comprising 1012 amino acids. One cannot extrapolate the teaching of the specification to the scope of the claims because the claims as written are drawn to an isolated polypeptide and a composition comprising variants of SEQ.ID.NO;2 i.e., isolated polypeptide comprising 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37 or 95% identical to 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 . Neither the specification nor the art of record define which amino acid residues

Art Unit: 1645

from 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or SEQ.ID.NO: 3, 17, or 25-37 are critical for being recognizable by antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2.

One cannot extrapolate the teaching of the specification to the scope of the claims because the claims because the claims as written are drawn to undefined polypeptides, wherein the three dimensional structure of the amino acids comprised within the polypeptides are unknown and neither the specification nor the art of record define which amino acid residues of SEQ ID NO:2 are critical for binding to an antibody that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2, Coleman et al. (Research in Immunology, 1994; 145(1): 33-36) teach that single amino acid changes in an antigen can effectively abolish antibody antigen binding. Furthermore, Abaza et al. (Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444, see abstract in particular) teach single amino acid substitutions outside the antigenic site on a protein affects antibody binding. Clearly if antibody binding is abolished, it is because of the alteration of the conformation of the epitope to which the antibody binds. Given the clear teaching drawn to conformation alteration with even a single amino acid change, clearly it would be expected that amino acid residues outside of the antigenic epitope, not native to SEQ ID NO:2 would alter the conformation of that epitope in the polypeptide comprising and that it could not be predicted, nor would it be expected that a structurally altered polypeptide would be recognizable by antibodies that would bind to SEQ ID NO:2.

Clearly the effects of the undefined alteration of about 5-25 amino acids of the claimed polypeptide on the structure of the molecule (95% of 29-533, 217-674, 688-1012, 29-1012 of SEQ.ID.NO: 2 or a polypeptide comprising an amino acid sequence of at least 95% identical to SEQ.ID.NO: 3, 17, or 25-37) cannot be predicted and given the teachings set forth above, it is clear that one could not predictably identify the undefined structure of the claimed polypeptide is recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2.

The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predictably make or identify the claimed antibodies with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1645

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 2, 21, 27, 28, 31, 32, 37, 38, 42-43, 48, 49, 50, 53, 54 , 59, 60, 61, 64, 65, 70, 71-73, 76, and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Caldwell et al., Infection and Immunity 31 (3): 1161-76, 1981 (IDS) as evidenced by Mygind et al. FEMS Microbiol. Lttrs, 186:163-169, 2000.

Claims are drawn to an isolated polypeptide and a composition comprising an amino acid sequence at least 95% identical to SEQ.ID.NO:3,17 or 25-37 or amino acids 29-533 of SEQ ID NO: 2 , 217-674 of SEQ ID NO: 2, 688-1012 of SEQ ID NO: 2, 29-1012 of SEQ ID NO: 2 , wherein said polypeptide is recognizable by an antibody preparation that specifically binds to a polypeptide consisting of the amino acid sequence of SEQ ID NO: 2, said composition comprises a carrier and an adjuvant , said composition is administered to a mammal.

It is noted that the specification on page 4 teaches that SEQ ID NO:2 has approximately 105-115 MW protein and said protein comprises fragments, therefore, the following reference is applied

Caldwell et al disclose an isolated Chlamydial outer membrane complexes (COMC) of *C. trachomatis* serovar L2/434/Bu as noted within Organisms and growth conditions, pp. 1162, The COMC preparations are as isolated and analyzed via SDS-PAGE procedures, see in particular pp. 1162-1163, by Sarkosyl extraction of intact elementary bodies and Figs 2, 3, 5 and 8 showing full length or fragment components (smaller molecular weights) of COMC preparation with molecular weight ranging from approximately 45kD-115kD determined by SDS-PAGE, see in particular Figure 2 and p. 1164, column 1, lines 38-39 and Figure 8. The protein and fragments (peptides) are substantially purified by SDS PAGE, see in particular Figure 2 and p. 1164, column 1, lines 38-39. The peptide composition optionally include suitable pharmaceutical carrier, diluents and/or adjuvants in emulsion/mixture. The peptides are immunogenic in a mammal (mice , see page 1163, right column, last paragraph), therefore would induce cell mediated response. Caldwell discloses high molecular weight protein 105-115 kD but fails to note the inherent property of the amino acid sequence of an isolated polypeptide comprising SEQ ID NO:2 , SEQ.ID.NO:3,17 or 25-37 or amino acids 29-533 of SEQ ID NO: 2 , 217-674 of SEQ ID NO: 2, 688-1012 of SEQ ID NO: 2, 29-1012 of SEQ ID NO: 2. However, SEQ.ID.NO:2 comprises 1012 amino acids and approximately has 105-115 kd molecular weight protein as each amino acid is roughly 110 daltons. Therefore, high molecular weight protein reads on SEQ.ID.NO:2 and a polypeptide comprising fragments of SEQ.ID.NO:2. Further as evidenced by Mygind, instant PmP or putative membrane protein of the claims is present in the *Chlamydia trachomatis* L2 (LGV-II/434/Bu) strain within the outer membrane complex . The isolated strain is the same as that sequenced disclosed in the specification. As no difference in the starting material or

Art Unit: 1645

procedures are noted and the analysis using SDS-PAGE provide for the isolated polypeptides and smaller immunopositive fragments of *C. trachomatis* LGV-II, the isolated peptide especially 105 kd are deemed to inherently correspond to the isolated sequence SEQ.ID.NO:2 as claimed and thus meet all limitations of the claims absent convincing factual evidence to the contrary. Since the Office does not have the facilities for examining and comparing applicants' polypeptide with the peptide and composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594. Thus, Caldwell et al clearly anticipates the claimed invention.

Remarks

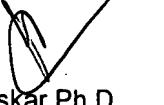
10. No claims are allowed.

Conclusion

11. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m except First Friday of each bi-week. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


Padma Baskar Ph.D

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

